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(56) Documents Cited  
**US 4108166 A**

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(54) Abstract Title  
**Body monitoring apparatus**

(57) Portable ECG monitoring apparatus comprises a sensor device 1 detachable from a monitoring device 2. The sensor device includes ECG sensors attached via cabling 5 to a connector 4. The sensor device 1 and monitoring device 2 are connected by attaching the connector 4 to the monitoring device 2, which provides a watertight seal for the apparatus and prevents access to any internal components in the monitoring device 2.

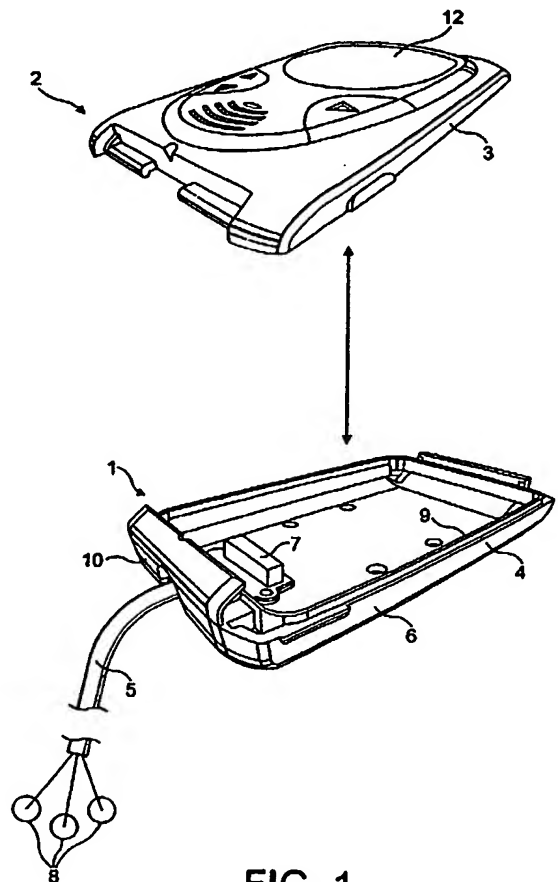
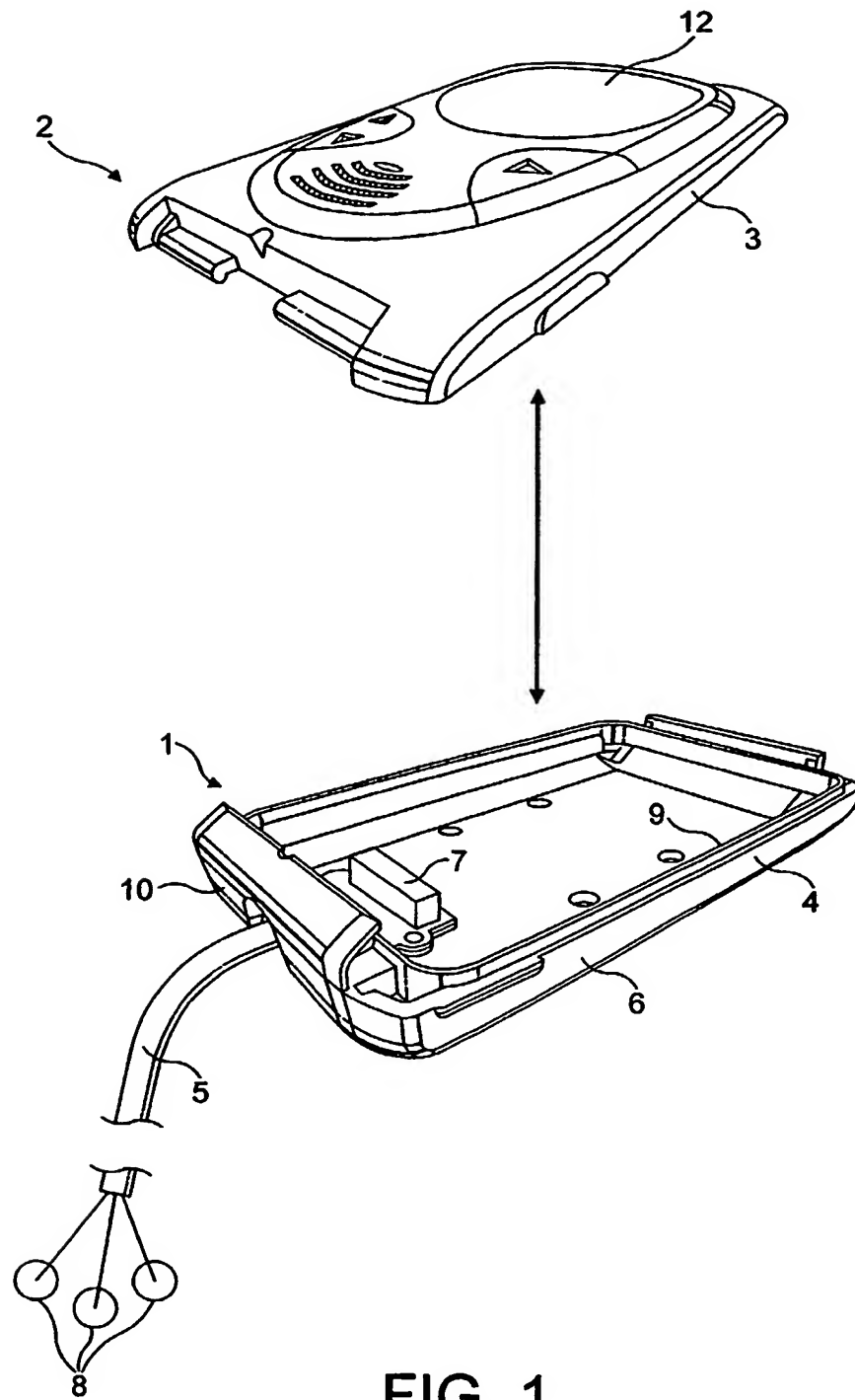


FIG. 1



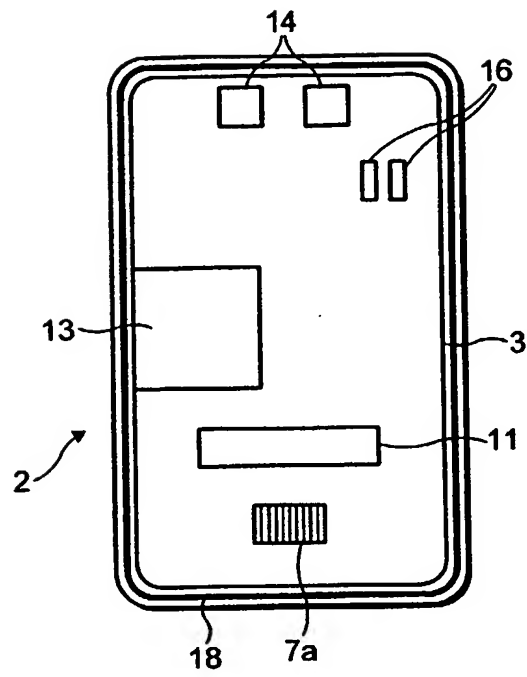


FIG. 2

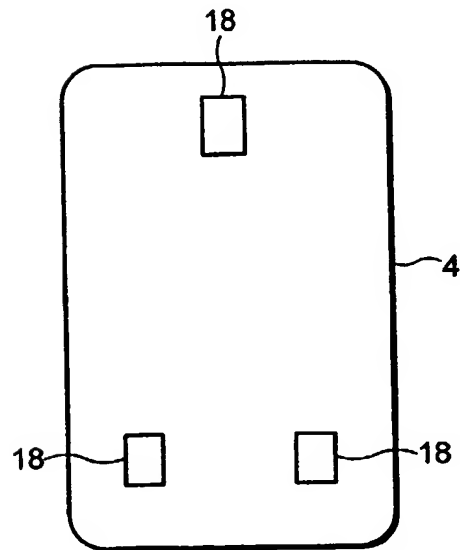


FIG. 3

BODY MONITORING APPARATUS

This invention relates to body monitoring apparatus, such as, for example, ECG monitoring apparatus.

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Body monitoring apparatus generally includes physiological sensors, a monitoring device and cables connecting the sensors to the monitoring device. The sensors are attached to a patient's body to detect physiological signals and may be, for example, electrocardiogram (ECG) electrodes, electroencephalogram (EEG) electrodes or blood oxygen sensors. For example, in ECG monitoring apparatus an electrocardiogram signal is measured as the difference in potential between a set of electrodes placed externally on the body of the patient. This allows the cardiac activity to be measured.

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In ambulatory monitoring the complete electronic apparatus is miniaturised and battery operated, adapted for wearing on the patient's body. WO94/26164 describes one known ambulatory monitoring apparatus, and is incorporated herein by reference.

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In all types of body monitoring apparatus it is advantageous for safety reasons that the patient is electrically isolated from the apparatus in use. In particular that access to the power source and other electrical connections in the monitoring device are prevented.

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According to the invention, there is provided body monitoring apparatus including a sensor device for

detecting physiological signals and a monitoring device,  
the monitoring device including a first part of a casing  
and an electronics module, the sensor device including a  
second part of a casing, wherein a completed casing which  
5 surrounds the electronics module is provided by the first  
and second parts attached together when the sensor device  
is connected to the monitoring device.

Of the completed casing the first and second parts are  
10 the only detachable parts. These parts are designed to  
be detached by only authorised personnel and not the  
user. The user will regard the device as one sealed  
unit.

15 Preferably, the sensor device includes means for sensing  
potentials at points on the patient's body. In the  
embodiment the sensing means is permanently attached or  
incorporated into the sensor device. It is not possible  
to change the sensing means without detaching the sensor  
20 device from the monitoring device, i.e. splitting the  
completed casing apart.

Advantageously, the completed casing is watertight.  
Therefore the device can continue to operate even when  
25 exposed to moisture. Because the casing has only two  
parts, only one watertight seal is required.

The electronics module of the monitoring device in the  
embodiment includes a power source which can only be  
30 removed when the sensor device is not connected to the  
monitoring device. Detaching the sensor device from the  
monitoring device in the embodiment automatically shuts  
down the electronics. Therefore, the device cannot be  
damaged by removing the power source while the

electronics are fully operational. Also, because the power source is inaccessible to the patient, a high power power source can be included in the apparatus.

- 5 The present invention also relates to a cabling device, a sensor device and a monitoring device all for use in the body monitoring apparatus as defined above.

For a better understanding of the present invention,  
10 specific embodiments according to the invention will now be described by way of example, with reference to the accompanying drawings, in which

Figure 1 shows body monitoring apparatus according to the invention,

- 15 Figure 2 shows the underside of the monitoring device part of the apparatus, and

Figure 3 shows a modified sensor device part of the apparatus, in which electrodes are incorporated.

- 20 In Fig. 1, portable body monitoring apparatus is provided by a sensor device 1 and a monitoring device 2. The monitoring device 2 includes a first part 3 of a casing, and an electronics module 11 (Fig. 2). The sensor device 1 includes sensors 8 which may be, for example, ECG  
25 electrodes for attaching to the patient's body. The sensor device includes a cable 5 linking the sensors 8 to a connector 4. The connector 4 includes a second part 6 of the casing.

- 30 In use, the sensor device 1 is electrically connected to the monitoring device 2 by an electrical interconnect 7 in the connector 4 and a corresponding interconnect 7a in

the monitoring device. The monitoring device 2 can then receive physiological data from the sensors 8 via the connector 4 and the cable 5.

5 Physiological data is received by the electronics module 11 in the monitoring device 2 and (depending on the particular electronics provided) may be displayed upon a front display panel 12 and/or transmitted to a remote station and/or stored in a memory device 13 for future  
10 display or transfer to other equipment (such as, for example, a personal computer). The monitoring device 2 may respond to the physiological data directly to produce an alarm or other indication to the patient or medical staff. The memory device 13 may be any suitable storage  
15 medium such as a magnetic cassette or solid state memory card.

The monitoring device 2 also includes batteries 14 and control switches 16 for configuring the monitoring  
20 device.

In the embodiment, the first part 3 of the casing is substantially planar and has a single opening in the back which extends substantially over the whole plan area of  
25 the casing. When the connector 4 is not connected to the monitoring device 2, the electronics in the monitoring device 2 are exposed and can be accessed through the opening. The medical staff are therefore able to replace the batteries 14 in the device, set control switches 16,  
30 and remove and replace the storage medium.

The second part 6 of the casing is provided by the external structure of the connector 4, which is a rigid moulding. When the connector 4 is connected to the back of the monitoring device 2 the first 3 and second 6 parts of the casing are attached together and the casing is thus completed. At the same time, electrical connection is provided between the sensors 8 and the monitoring device 2.

The entry of the cable 5 to the connector 4 is sealed by an elastomeric strain relief grommet 10. The grommet 10 is permanently fixed in place. The rigid moulding and elastomeric grommet assembly for the connector 4 is cheaper than alternative connector designs in which the electrical assembly is overmoulded with elastomers.

Connector mis-mating is prevented by the physical design of the connector 4. The connector can only be attached in one orientation.

When the casing is completed, no access is possible to the internal components 7a, 11, 13, 14 and 16 of the monitoring device 2. Therefore when the device 2 is in use on a patient, the patient is substantially electrically isolated from the device. It is not possible to access any of the electrical connections within the device (for example battery 14 terminals, memory card connections, conductive chassis) which could otherwise present a risk to the patient's safety. This allows additional battery capacity to be provided in the apparatus without increasing the risk to the patient's safety.



A watertight seal is provided between the first 3 and second 6 parts of the completed casing. This is provided by a foamed silicon rubber 'O' ring 18 located in a continuous channel running around the periphery of the opening in the first part 3 of the casing. A raised edge 9 of the second part 6 of the casing presses against this gasket ('O' ring) to form a seal. The completed casing is waterproof, and therefore advantageously resistant to fluid ingress, both in the patient environment (perspiration, ablutions, incontinence, rain) and in the medical environment (cleaning and disinfecting).

Thus a fluid-tight casing formed of two readily detachable parts is provided.

It is generally recognised as more difficult to provide seals for covers that are readily detachable from a body than to provide permanent fixed seals. In the embodiment the single connector 4 provides a simple and effective method for sealing the casing using a minimum number of opening seals.

Different types of physiological sensors and cables are available. The body monitoring apparatus of the embodiment incorporates circuitry which allows the monitoring device 2 to determine firstly if a sensor device 1 has been connected, and if so, what type of cable or sensor is being used. This "autosensing feature" is implemented using a coded interconnection of connector pins provided in the interconnect 7. This simplifies the set up procedure when changing sensors by minimising the

required user interaction. In this way, the apparatus can detect whether a connector has been attached and therefore whether the casing is complete or incomplete. If a connector 4 is not attached, the monitoring device  
5 can enter a "safe mode" to prevent corruption of any recorded or internal data and/or to conserve battery life.

Additional circuitry which is specific to the  
10 physiological sensor type may be built as part of the connector 4. For example, a twelve lead ECG electrode connections, defibrillator protection and signal acquisition circuitry could be integrated as a patient cable.

15 The large area of the connector 4 allows the sensor device 1 to alternatively be manufactured as a direct electrode accessory, as shown in Figure 3. In this, the connector 4 includes well separated conductive areas 18  
20 which act as the electrodes when in contact with the patient. This arrangement is applicable to an ECG event recorder for example.

As an alternative to the sensors, the connector 4 can  
25 instead be provided with cabling for connecting the monitoring device 2 to other external equipment (for example, a personal computer). The connector can then be attached to the monitoring device 2 to provide a serial data communications link for downloading data stored in  
30 the storage medium to the external equipment. This may be downloaded using a format such as RS-232 or USB. With this design, it is not possible for both the sensors and

the external equipment to be simultaneously connected to the monitoring device, and therefore avoids this potentially hazardous situation.

CLAIMS

1. Body monitoring apparatus including a sensor device for detecting physiological signals and a monitoring  
5 device, the monitoring device including a first part of a casing and an electronics module, the sensor device including a second part of the casing, wherein a completed casing which surrounds the electronics module is provided by the first and second parts attached  
10 together when the sensor device is connected to the monitoring device.
2. Body monitoring apparatus according to claim 1,  
15 wherein the completed casing is watertight.
3. Body monitoring apparatus according to claim 2,  
wherein a watertight seal between the first and second parts of the completed casing is formed between an 'O' ring in a channel formed on one of first and second parts  
20 of the casing and a raised edge formed on the other part.
4. Body monitoring apparatus according to claim 1, 2 or 3, the electronics module including a power source which can be removed when the sensor device is not connected to  
25 the monitoring device.
5. Body monitoring apparatus according to claim 1, 2, 3 or 4, the electronics module including a storage medium which can be removed when the sensor device is not  
30 connected to the monitoring device.

6. Body monitoring apparatus according to any one of the preceding claims, the electronics module including an internal control switch which can be accessed when the sensor device is not connected to the monitoring device.

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7. Body monitoring apparatus according to any one of the preceding claims, including circuitry for detecting whether the casing is complete or incomplete.

10 8. Body monitoring apparatus according to claim 7, the circuitry including connector pins.

9. Body monitoring apparatus according to any one of the preceding claims, wherein the sensor device includes  
15 means to sensing potentials at points on a living body.

10. Body monitoring apparatus substantially as hereinbefore described with reference to and/or substantially as illustrated in the accompanying  
20 drawings.

11. A cabling device for use in the body monitoring apparatus as claimed in claim 9.

25 12. A sensor device for use in the body monitoring apparatus as claimed in any one of claims 1 to 10.

13. A monitoring device for use in the body monitoring apparatus as claimed in any of claims 1 to 10.

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Amendments to the claims have been filed as follows

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CLAIMS

1. Body monitoring apparatus including a sensor device  
for detecting physiological signals and a monitoring  
5 device, the monitoring device comprising an electronics  
module and a first part of a casing shaped so as to allow  
access to the electronics module, the sensor device  
including a second part of the casing wherein a completed  
casing which surrounds the electronics module is provided  
10 by the first and second parts attached together when the  
sensor device is connected to the monitoring device.
2. Body monitoring apparatus according to claim 1,  
wherein the completed casing is watertight.  
15
3. Body monitoring apparatus according to claim 2,  
wherein a watertight seal between the first and second  
parts of the completed casing is formed between an 'O'  
ring in a channel formed on one of first and second parts  
20 of the casing and a raised edge formed on the other part.
4. Body monitoring apparatus according to claim 1, 2 or  
3, the electronics module including a power source which  
can be removed when the sensor device is not connected to  
25 the monitoring device.
5. Body monitoring apparatus according to claim 1, 2, 3  
or 4, the electronics module including a storage medium  
which can be removed when the sensor device is not  
30 connected to the monitoring device.

6. Body monitoring apparatus according to any one of the preceding claims, the electronics module including an internal control switch which can be accessed when the sensor device is not connected to the monitoring device.

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7. Body monitoring apparatus according to any one of the preceding claims, including circuitry for detecting whether the casing is complete or incomplete.

10 8. Body monitoring apparatus according to claim 7, the circuitry including connector pins.

9. Body monitoring apparatus according to any one of the preceding claims, wherein the sensor device includes  
15 means to sensing potentials at points on a living body.

10. Body monitoring apparatus substantially as hereinbefore described with reference to and/or substantially as illustrated in the accompanying  
20 drawings.

11. A cabling device for use in the body monitoring apparatus as claimed in claim 9.

25 12. A sensor device for use in the body monitoring apparatus as claimed in any one of claims 1 to 10.

13. A monitoring device for use in the body monitoring apparatus as claimed in any of claims 1 to 10.

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**Claims searched:** 1-13

**Examiner:** Eamonn Quirk  
**Date of search:** 2 October 2001

**Patents Act 1977**  
**Search Report under Section 17**

**Databases searched:**

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:  
UK CI (Ed.S): G1N( NAGBR, NAGCR, NAGDR, NECG, NEEG, NESS)  
Int CI (Ed.7): A61B (5/0404)  
Other: Online: WPI, EPODOC, JAPIO

**Documents considered to be relevant:**

Category	Identity of document and relevant passage	Relevant to claims
X	US 4 108 166 (Walther Schmid) whole document	1,2,4,6,9

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.